FEB 0 4 2003

510(k) SUMMARY OF INFORMATION

K023540

SUBMITTER: ValuMed
1439 Live Oak Street. Suite A
Niceville, Florida 32578
(850) 897-3321 – Phone
(850) 897-1280 – Fax

CONTACT PERSON: Wynne Barnes

DATE PREPARED: January 13, 2003

CLASSIFICATION NAME: Cover, Barrier, Protective

COMMON NAME: Equipment Covers

PROPRIETARY NAME: Cover All Equipment Covers

PREDICATE DEVICES:
Sterile Equipment Covers – Custom Medical Products - K931417
Equipment Covers – United States Surgical - K964699
Equipment Snap Covers – Advance Medical Designs -K850959

DEVICE DESCRIPTION: ValuMed's Cover Alls, the Sterile Equipment Covers by Custom Medical Products(K931417), Equipment Covers by United States Surgical(K964699) and the Equipment Snap Covers by Advance Medical Designs(K850959) consist of various sizes and shapes of polyethylene covers that are positioned on surgical equipment. The covers are used to maintain a sterile field and as an aid in the clean up of equipment after surgery.

INDENTED USE: These equipment covers are intended to cover equipment and are not intended to be used as patient drapes or have patient contact.

SUBSTANTIAL EQUIVALENCE:

ValuMed's Equipment Covers are substantially equivalent to the above-mentioned predicate devices in that they provide the following characteristics:

- Intended use is the same
- Size, configuration, color are similar
- Made of polyethylene
- Physical properties are similar

NON-CLINICAL TEST DATA:

Testing conducted: Seal Peel Test, Tear Resistance Test, and Flammability Test

ATTACHMENT 8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2003

Mr. Thomas E. Cottone
President
ValuMed
1439 Live Oak Street, Suite A
Niceville, Florida 32578

Re: K023540
Trade/Device Name: Covers All Equipment Covers Banded Bags & Dome Bags Various Models, Sterile Non-Sterile
Regulation Number: None
Regulation Name: Cover, Barrier, Protective
Regulatory Class: Unclassified
Product Code: MMP
Dated: December 12, 2002
Received: December 20, 2002

Dear Mr. Cottone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

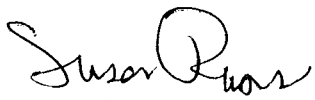
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K023540

Device Name: CoverAlls-Equipment Covers

STATEMENT OF INDICATIONS FOR USE

The various sizes of Polyethylene Equipment Covers are intended to be used to cover medical equipment in order to maintain the sterile field and as an aid in the clean up of equipment after surgery. These covers are not intended to be used as patient drapes and do not have patient contact.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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